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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,494	08/17/2001	Trang T. Le	C-3320/1/US	5208

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,494	LE ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,10-25,28-53,62-83 and 86-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,10-25,28-53,62-83 and 86-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Extension of Time and Amendment with attachment filed 03/17/03.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 10, 11, 28, 29, 33-35, 39-42, 62-68, 77-83, 86-89 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, and 17-32, 34, and 36-39 of copending Application No. 09/932,500 ('500). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '500 application claims a process for preparing an oral fast-melt tablet formulation comprising wet granulating celecoxib together with binding agent; blending with the drug a saccharide having low moldability; blending the granules with at least one of a lubricant, a sweetening agent and a flavoring agent; and compressing the resulting blend into tablet. The process is found in claims 1 and 16. Claims 6 and 7 recite celecoxib as a COX-2 inhibitor. Claims

13 and 14 recite saccharide having low moldability. The amount of drug is found in claims 9-12. Therefore, those of ordinary skill would expect a similar fast-melt tablet comprising celecoxib from the use of the claimed invention given the claims of '500. There are no unusual and/or unexpected results, which would be rebut prima facie obviousness. As such, the instant claims would have been obvious given the claims of '500, which set out a similar process for preparing an oral fast-melt tablet formulation using the same steps, materials, machinery, and conditions as claimed herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 10-16, 18-21, 23-25, 28-44, 46-49, 51-53, 62-83, and 86-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Talley et al. US 5,760,068.

Mizumoto teaches quick-dissolved compressed tablet comprising saccharide having high moldability and saccharide having low moldability (columns 6-7), drug, and additive agents (columns 13-19, claims 1-6). The drug used is in an amount of about 50%, and is not limited but include both analgesic and anti-inflammatory drugs (column

7). The method for preparing the tablet is disclosed in columns 12-13. The composition further comprises lubricant, *e.g.*, magnesium stearate, sucrose fatty acid ester, polyethylene glycol, or talc (column 13, lines 52-55). The hardness, strength, and disintegration time is disclosed in column 11.

Mizumoto does not specifically teach the claimed active agent to be a COX-2 inhibitor. However, COX-2 inhibitor is a well-known analgesic agent, particularly, anti-inflammatory, which can be used in conjunction with other analgesic agents.

Talley '068 teaches COX-2 such as celecoxib is a known anti-inflammatory agent. Thus it would have been obvious for one of ordinary skill in the art to prepare the quick-dissolved formulation of Mizumoto using the COX-2 inhibitor, such as celecoxib in view of the teachings of Talley, because the references teach the advantageous results in the use of a well-known anti-inflammatory agent.

The examiner notes that the cited references are silent as to the amounts of glidant, and wetting agent being claimed in claims 18-20 and 23-25. However, it is the position of the examiner that no criticality is seen in the particular amounts since the prior art in using the claimed ingredients, obtains the same results desired by the applicant, *e.g.*, tablet comprising analgesic agent having disintegration rate of 1-40 seconds. See also *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Claims 1, 17, 22, 42, 45, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. and Talley et al., in view of Jain et al. US 6,316,029.

Mizumoto and Talley are relied upon for the reason stated above. The references do not teach the specific glidant, and wetting agent.

Jain teaches process for preparing rapidly disintegrating solid oral dosage form comprising sodium lauryl sulfate and silicon dioxide (columns 8-9). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to use the sodium lauryl sulfate and silicon dioxide in view of the teaching of Jain to prepare the quick-dissolved formulation of Mizumoto since sodium lauryl sulfate and silicon dioxide are well known tabletting aids. The expected result would be compressed tablet having good hardness and dissolved quickly upon contact with fluid.

Response to Arguments

Applicant's arguments filed 03/17/03 have been fully considered but they are not persuasive.

Claims 1-6, 10-16, 18-21, 23-44, 46-49, 51-56, and 60-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, and Nakao et al. US 6,277,878.

Applicant argues that Nakao does not teach celecoxib among the selective COX-2 inhibitor, nor does Nakao teach or suggest means to inhibit agglomeration. Hence, the 103(a) rejection over Mizumoto et al., and Nakao et al. has been withdrawn.

Claims 1-3, 10-16, 18-21, 23-25, 28-44, 46-49, 51-53, 62-83, and 86-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Talley et al. US 5,760,068.

Applicant argues that Mizumoto represents "state of the art" formulation technology useful for preparing an oral fast-melt tablet at the time of the present invention. However, when applying this technology to a poorly soluble selective COX-2 inhibitory drug, in particular to celecoxib, certain changes arise (see specification page 5). Accordingly, applicant alleges that Mizumoto does not teach the solution to overcome the problem faced by the present inventors, namely incorporating in the process of "means to inhibit agglomeration of the drug", wherein of "means to inhibit agglomeration of the drug" can be any such means, as set forth in the specification at page 8. Contrary to the applicant's argument, the process taught by Mizumoto is useful for so many poorly soluble drugs, such as the NSAIDs disclosed in column 8. It appears that Mizumoto is able to overcome the undesirable problem to obtain the results desired by the applicant, *e.g.*, an intrabucally dosage form showing quick disintegration and dissolution in the buccal cavity and have an adequate hardness (see abstract). In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "means to inhibit agglomeration of the drug" can be any such means, as set forth in the specification at page 8) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read

into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 1, 17, 22, 42, 45, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. and Talley et al., in view of Jain et al. US 6,316,029.

Applicant argues that Jain fails to teach two elements, namely celecoxib and means to inhibit agglomeration. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Jain is cited in view of Mizumoto et al. and Talley et al. Furthermore, it is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Jain is relied upon solely for the teaching of sodium lauryl sulfate and silicon dioxide in a rapidly disintegrating solid oral dosage form.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600